

# Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV

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Appendix B, Table 10. Antiretroviral Dosing Recommendations in Persons with Renal or Hepatic Insufficiency (Last updated December 18, 2019; last reviewed December 18, 2019) (page 1 of 6)

The older ARV drugs ddI, d4T, FPV, IDV, NFV, SQV, and TPV are no longer commonly used in clinical practice and have been removed from this table. Please refer to the July 10, 2019, guidelines in the Guidelines Archive section of AIDS*info* or to the FDA product labels for these drugs for recommendations on dosing in persons with renal or hepatic insufficiency.

See the reference section at the end of this table for CrCl calculation formulas and criteria for Child-Pugh classification.

Generic Name (Abbreviations) Usual Daily Dose <sup>a</sup> Trade Name	Dosing in Persons with Renal Insufficiency	Dosing in Persons with Hepatic Impairment
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Some FDC products are not recommended in persons with different degrees of renal insufficiency. The recommendations for individual FDCs based on CrCl level are outlined below.

- CrCl <70 mL/min: Initiation of Stribild is not recommended.
- CrCl <50 mL/min: FDCs not recommended: Atripla, Combivir, Complera, Delstrigo, Dovato, Epzicom, Triumeq, or Trizivir.
- CrCl <30 mL/min: FDCs not recommended: Biktarvy and Truvada.
- CrCl <30 mL/min and not on HD: FDCs not recommended: Descovy, Genvoya, Odefsey, and Symtuza

• Crci <30 mL/min and not on HD: FDCs not recommended: Descovy, Genvoya, Odersey, and Symtuza.  The component drugs in some of the FDC products listed above may be prescribed as individual formulations with dose adjustment based						
	igs in some of the FDC product licated below in this table.	ts listed above	may b	e prescrit	ed as individual to	rmulations with dose adjustment based
NRTIs						
Abacavir (ABC) Ziagen	ABC 300 mg PO twice daily or ABC 600 mg PO once daily	No dose adjustment necessary.			ry.	Child-Pugh Class A: ABC 200 mg PO twice daily (use oral solution)  Child-Pugh Class B or C:  Contraindicated
Emtricitabine	FTC 200 mg oral		ose b	y Formu	lation	No dose recommendation.
(FTC) Emtriva	capsule once daily or	CrCl (mL/ min)	Ca	psule	Solution	
	FTC 240 mg (24 mL) oral solution once daily	30–49	200 n 48 ho	ng every ours	120 mg every 24 hours	
		15–29	200 m 72 ho	ng every ours	80 mg every 24 hours	
	<15	200 m 96 ho	ng every ours	60 mg every 24 hours		
		On HD <sup>b</sup>	200 n 24 ho	ng every ours	240 mg every 24 hours	
Lamivudine	3TC 300 mg PO once	CrCl (mL/m	in)		Dose	No dose adjustment necessary.
(3TC)	daily	30–49			ery 24 hours	
Epivir	or 3TC 150 mg PO twice	15–29		x 150 mg very 24 h	, then 100 mg ours	
daily	5–14		x 150 mg very 24 h	, then 50 mg ours		
		<5 or on HDb 1 x 50 mg, then 25 mg every 24 hours				
Tenofovir Alafenamide	Vemlidy is available as a 25-mg tablet for the	CrCl (mL/min)  One tablet once dail  On HDb  One tablet once dail		1 1 1	Child-Pugh Class B or C: Not recommended	
(TAF)	treatment of HBV.			+		- Control Way
<u>Vemlidy</u>		ON HU		One tal	net once daily.	

## Appendix B, Table 10. Antiretroviral Dosing Recommendations in Persons with Renal or Hepatic Insufficiency (Last updated December 18, 2019; last reviewed December 18, 2019) (page 2 of 6)

Generic Name (Abbreviations) Trade Name	Usual Daily Dose <sup>a</sup>		ersons with Renal ufficiency	Dosing in Persons with Hepatic Impairment	
NRTIs, continued					
Tenofovir	TAF for HIV treatment	CrCl (mL/min) Dose		Child-Pugh Class A or B: No dose	
Alafenamide/ Emtricitabine	is only available as a component of	<30 and not on HD Not recommended		adjustment	
(TAF/FTC) FDC tablets (i.e., in		<30 and on HD <sup>b</sup>	One tablet once	Child-Pugh Class C: No dose	
Descovy	Descovy, Genvoya, Odefsey, Biktarvy, and Symtuza).		daily.	recommendation	
	TAF 10 mg PO daily with EVG/c (Genvoya) or DRV/c (Symtuza)				
	TAF 25 mg PO daily in other FDC tablets				
Tenofovir Disoproxil	TDF 300 mg PO once	CrCl (mL/min)	Dose	No dose adjustment necessary.	
Fumarate	daily	30–49	300 mg every 48 hours		
(TDF) Viread		10–29 300 mg twice weekly (every 72–96 hours)			
		<10 and not on HD	No recommendation		
		On HD <sup>b</sup>	300 mg every 7 days		
Tenofovir Disoproxil Fumarate/			Dose	No dose recommendation.	
Emtricitabine	,		One tablet every 48 hours		
(TDF/FTC) Truvada		<30 or on HD	Not recommended		
Tenofovir Disoproxil	One tablet PO once	CrCl (mL/min) Dose		No dose recommendation.	
Fumarate/Lamivudine	daily	<50 or on HD	Not recommended		
(TDF/3TC) Cimduo				J	
Zidovudine	ZDV 300 mg PO twice	CrCl (mL/min)	Dose	No dose recommendation.	
(ZDV) Retrovir	daily	<15 or on HDb 100 mg three times a day or 300 mg once daily			
NNRTIs				1	
Doravirine	One tablet PO once	No dose adjustment	t required in mild	Child-Pugh Class A or B: No dose	
(DOR)	daily	moderate, or severe	renal impairment. Has	adjustment	
Pifeltro		not been studied in on HD.	individuals with ESRD or	Child-Pugh Class C: Not studied	
Doravirine/Tenofovir Disoproxil Fumarate/ Lamivudine	One tablet PO once daily	Not recommended if CrCl <50 mL/min.		Child-Pugh Class A or B: No dose adjustment	
(DOR/TDF/3TC)  Delstrigo				Child-Pugh Class C: Not studied	

### Appendix B, Table 10. Antiretroviral Dosing Recommendations in Persons with Renal or Hepatic Insufficiency (Last updated December 18, 2019; last reviewed December 18, 2019) (page 3 of 6)

Generic Name (Abbreviations) Trade Name	Usual Daily Dose <sup>a</sup>	Dosing in Persons with Renal Insufficiency	Dosing in Persons with Hepatic Impairment
NNRTIs, continued			
Efavirenz (EFV) Sustiva	EFV 600 mg PO once daily on an empty stomach, preferably at bedtime	No dose adjustment necessary.	No dose recommendation; use with caution in patients with hepatic impairment.
Efavirenz/Tenofovir Disoproxil Fumarate/ Emtricitabine (EFV/TDF/FTC) Atripla	One tablet PO once daily on an empty stomach, preferably at bedtime	Not recommended if CrCl <50 mL/min. Instead, use the individual component ARVs and adjust TDF and FTC doses according to CrCl level.	No dose recommendation; use with caution in patients with hepatic impairment.
Efavirenz 600 mg/ Tenofovir Disoproxil Fumarate/Lamivudine (EFV/TDF/3TC) Symfi	One tablet once daily on an empty stomach, preferably at bedtime	Not recommended if CrCl <50 mL/min or if patient is on HD. Instead, use the individual component ARVs and adjust TDF and 3TC doses according to CrCl level.	Not recommended for patients with moderate or severe hepatic impairment. Use with caution in patients with mild hepatic impairment.
Efavirenz 400 mg/ Tenofovir Disoproxil Fumarate/Lamivudine (EFV/TDF/3TC) Symfi Lo	One tablet once daily on an empty stomach, preferably at bedtime	Not recommended if CrCl <50 mL/min or if patient is on HD. Instead, use the individual component ARVs and adjust TDF and 3TC doses according to CrCl level.	Not recommended for patients with moderate or severe hepatic impairment. Use with caution in patients with mild hepatic impairment.
Etravirine (ETR) Intelence	ETR 200 mg PO twice daily	No dose adjustment necessary.	Child-Pugh Class A or B: No dose adjustment Child-Pugh Class C: No dose
Nevirapine (NVP)	NVP 200 mg PO twice daily	No dose adjustment for patients with renal impairment.	recommendation  Child-Pugh Class A: No dose adjustment
Viramune or Viramune XR	or  NVP 400 mg PO once daily (using Viramune XR formulation)	Patients on HD should receive an additional dose of NVP 200 mg following each dialysis treatment.	Child-Pugh Class B or C: Contraindicated
Rilpivirine (RPV) Edurant	RPV 25 mg PO once daily	No dose adjustment necessary.	Child-Pugh Class A or B: No dose adjustment Child-Pugh Class C: No dose recommendation
Rilpivirine/Tenofovir Alafenamide/ Emtricitabine (RPV/TAF/FTC) Odefsey	One tablet PO once daily	In Patients on Chronic HD:  • One tablet once daily. On HD days, administer after dialysis.  Not recommended in patients with CrCl <30 mL/min who are not receiving chronic HD.	Child-Pugh Class A or B: No dose adjustment Child-Pugh Class C: No dose recommendation
Rilpivirine/Tenofovir Disoproxil Fumarate/ Emtricitabine (RPV/TDF/FTC) Complera	One tablet PO once daily	Not recommended if CrCl <50 mL/min. Instead, use the individual component ARVs and adjust TDF and FTC doses according to CrCl level.	Child-Pugh Class A or B: No dose adjustment Child-Pugh Class C: No dose recommendation

### Appendix B, Table 10. Antiretroviral Dosing Recommendations in Persons with Renal or Hepatic Insufficiency (Last updated December 18, 2019; last reviewed December 18, 2019) (page 4 of 6)

Generic Name (Abbreviations) Trade Name	Usual Daily Dose <sup>a</sup>	Dosing in Persons with Renal Insufficiency	Dosing in Persons with Hepatic Impairment
NNRTIs, continued			
Rilpivirine/ Dolutegravir	One tablet PO once daily with food	No dose adjustment necessary.  In patients with CrCl <30 mL/min, monitor	Child-Pugh Class A or B: No dose adjustment
(RPV/DTG)  Juluca		closely for adverse effects.	Child-Pugh Class C: No dose recommendation
Pls			
Atazanavir (ATV)	ATV 400 mg PO once daily	No dose adjustment for patients with renal dysfunction who do not require HD.	Child-Pugh Class A: No dose adjustment
Reyataz	or (ATV 300 mg plus RTV 100 mg) PO once daily	In ARV-Naive Patients on HD:  • (ATV 300 mg plus RTV 100 mg) once daily	Child-Pugh Class B: ATV 300 mg once daily (unboosted) for ARV-naive patients only
		In ARV-Experienced Patients on HD:  • ATV and ATV/r are not recommended	Child-Pugh Class C: Not recommended
			RTV boosting <b>is not recommended</b> in patients with hepatic impairment.
Atazanavir/Cobicistat (ATV/c) Evotaz	One tablet PO once daily	If Used with TDF:  • Not recommended if CrCl <70 mL/min	Not recommended in patients with hepatic impairment.
<b>Darunavir</b> (DRV) <i>Prezista</i>	In ARV-Naive Patients and ARV-Experienced Patients with No DRV Resistance Mutations: • (DRV 800 mg plus RTV 100 mg) PO once daily with food	No dose adjustment necessary.	In Patients with Mild-to-Moderate Hepatic Impairment: No dose adjustment In Patients with Severe Hepatic Impairment: Not recommended
	In ARV-Experienced Patients with at Least One DRV Resistance Mutation:		
	(DRV 600 mg plus RTV 100 mg) PO twice daily		
Darunavir/Cobicistat (DRV/c)	One tablet PO once daily	If Used with TDF:  • Not recommended if CrCl <70 mL/min	Child-Pugh Class A or B: No dose adjustment
Prezcobix			Child-Pugh Class C: Not recommended
Darunavir/ Cobicistat/Tenofovir Alafenamide/ Emtricitabine	One tablet PO once daily	In Patients on Chronic HD:  • One tablet once daily. On HD days, administer after dialysis.	Not recommended for patients with severe hepatic impairment.
(DRV/c/TAF/FTC) Symtuza		Not recommended in patients with CrCl <30 mL/min who are not receiving chronic HD.	

### Appendix B, Table 10. Antiretroviral Dosing Recommendations in Persons with Renal or Hepatic Insufficiency (Last updated December 18, 2019; last reviewed December 18, 2019) (page 5 of 6)

Generic Name (Abbreviations) Trade Name	Usual Daily Dose <sup>a</sup>	Dosing in Persons with Renal Insufficiency	Dosing in Persons with Hepatic Impairment
Pls, continued			
Lopinavir/Ritonavir (LPV/r) Kaletra	(LPV/r 400 mg/100 mg) PO twice daily or (LPV/r 800 mg/200 mg) PO once daily	Avoid once-daily dosing in patients on HD.	No dose recommendation; use with caution in patients with hepatic impairment.
Ritonavir (RTV) <i>Norvir</i>	As a PI-Boosting Agent: • RTV 100–400 mg per day	No dose adjustment necessary.	Refer to recommendations for the primary (i.e., boosted) PI.
INSTIs			
Bictegravir/Tenofovir Alafenamide/ Emtricitabine (BIC/TAF/FTC)	One tablet once daily	Not recommended for use in patients with CrCl <30 mL/min.	Child-Pugh Class A or B: No dose adjustment  Child-Pugh Class C: Not recommended
Biktarvy			
Dolutegravir (DTG) Tivicay	or DTG 50 mg once daily or DTG 50 mg twice daily	No dose adjustment necessary.	Child-Pugh Class A or B: No dose adjustment  Child-Pugh Class C: Not recommended
Dolutegravir/ Abacavir/Lamivudine (DTG/ABC/3TC) Triumeq	One tablet once daily	Not recommended if CrCl <50 mL/min. Instead, use the individual component drugs and adjust 3TC dose according to CrCl.	Child-Pugh Class A: Patients with mild hepatic impairment require a dose reduction of ABC. Use the individual drugs instead of the FDC tablet in these patients.
			Child-Pugh Class B or C: Contraindicated due to the ABC component
Dolutegravir/ Rilpivirine (DTG/RPV)	One tablet PO once daily with food	No dose adjustment necessary.  In patients with CrCl <30 mL/min, monitor	Child-Pugh Class A or B: No dose adjustment
Juluca		closely for adverse effects.	Child-Pugh Class C: No dose recommendation
Elvitegravir/ Cobicistat/Tenofovir Alafenamide/ Emtricitabine	One tablet once daily	In Patients on Chronic HD:  One tablet once daily. On HD days, administer after dialysis.	In Patients with Mild-to-Moderate Hepatic Insufficiency: No dose adjustment necessary In Patients with Severe Hepatic
(EVG/c/TAF/FTC) Genvoya		Not recommended in patients with CrCl <30 mL/min who are not receiving chronic HD.	Insufficiency: Not recommended
Elvitegravir/ Cobicistat/Tenofovir Disoproxil Fumarate/ Emtricitabine	One tablet once daily	EVG/c/TDF/FTC should not be initiated in patients with CrCl <70 mL/min.  Discontinue EVG/c/TDF/FTC if CrCl declines to <50 mL/min while patient is on therapy.	In Patients with Mild-to-Moderate Hepatic Insufficiency: No dose adjustment necessary In Patients with Severe Hepatic
(EVG/c/TDF/FTC) Stribild			Insufficiency: Not recommended

#### Appendix B, Table 10. Antiretroviral Dosing Recommendations in Persons with Renal or Hepatic Insufficiency (Last updated December 18, 2019; last reviewed December 18, 2019) (page 6 of 6)

Generic Name (Abbreviations) Trade Name	Usual Daily Dose <sup>a</sup>	Dosing in Persons with Renal Insufficiency	Dosing in Persons with Hepatic Impairment					
INSTIs, continued	INSTIs, continued							
Raltegravir (RAL) Isentress Isentress HD	RAL 400 mg twice daily (using Isentress formulation) or RAL 1,200 mg once daily (using Isentress HD formulation only)	No dose adjustment necessary.	In Patients with Mild-to-Moderate Hepatic Insufficiency: No dose adjustment necessary In Patients with Severe Hepatic Insufficiency: No recommendation					
Fusion Inhibitor								
Enfuvirtide (T-20) Fuzeon	T-20 90 mg SQ twice daily	No dose adjustment necessary.	No dose adjustment necessary.					
CCR5 Antagonist								
Maraviroc (MVC) Selzentry	The recommended dose differs based on concomitant medications and potential for drug-drug interactions. See Appendix B, Table 8 for detailed dosing information.	In Patients with CrCl <30 mL/min or Patients Who Are on HD  Without Potent CYP3A Inhibitors or Inducers:  • MVC 300 mg twice daily; if postural hypotension occurs, reduce to MVC 150 mg twice daily  With Potent CYP3A Inducers or Inhibitors:  • Not recommended	No dose recommendations. MVC concentrations will likely be increased in patients with hepatic impairment.					
CD4 Post-Attachment		T	1					
Ibalizumab (IBA) Trogarzo	Loading dose: IBA 2,000 mg IV Maintenance dose: IBA 800 mg IV every 2 weeks	No dose adjustment recommended.	No recommendation.					

<sup>&</sup>lt;sup>a</sup> Refer to Appendix B, Tables 1–9 for additional dosing information.

**Key:** 3TC = lamivudine; ABC = abacavir; ARV = antiretroviral; ATV = atazanavir; ATV/c = atazanavir/cobicistat; ATV/r = atazanavir/ritonavir; BIC = bictegravir; CAPD = chronic ambulatory peritoneal dialysis; COBI = cobicistat; CrCI = creatinine clearance; CYP = cytochrome P; d4T = stavudine; ddl = didanosine; DOR = doravirine; DRV = darunavir; DRV/c = darunavir/cobicistat; DTG = dolutegravir; EC = enteric coated; EFV = efavirenz; ESRD = end stage renal disease; ETR = etravirine; EVG = elvitegravir; EVG/c = elvitegravir/cobicistat; FDA = Food and Drug Administration; FDC = fixed-dose combination; FPV = fosamprenavir; FTC = emtricitabine; HBV = hepatitis B virus; HD = hemodialysis; IBA = ibalizumab; IDV = indinavir; INSTI = integrase strand transfer inhibitor; IV = intravenous; LPV = lopinavir; LPV/r = lopinavir/ritonavir; MVC = maraviroc; NFV = nelfinavir; NNRTI = non-nucleoside reverse transcriptase inhibitor; NVP = nevirapine; PI = protease inhibitor; PO = orally; RAL = raltegravir; RPV = rilpivirine; RTV = ritonavir; SQ = subcutaneous; SQV = saquinavir; T-20 = enfuvirtide; TAF = tenofovir alafenamide; TDF = tenofovir disoproxil fumarate; TPV = tipranavir; XR = extended release: ZDV = zidovudine

<sup>&</sup>lt;sup>b</sup> On dialysis days, the patient should take the dose after the HD session.

Creatinine Clearance Calculation			
Male:	(140 - age in years) x (weight in kg) 72 x (serum creatinine)	Female:	(140 – age in years) x (weight in kg) x (0.85) 72 x (serum creatinine)

Child-Pugh Score				
Commonant	Points Scored			
Component	1	2	3	
Encephalopathy <sup>a</sup>	None	Grade 1–2	Grade 3–4	
Ascites	None	Mild or controlled by diuretics	Moderate or refractory despite diuretics	
Albumin	>3.5 g/dL	2.8–3.5 g/dL	<2.8 g/dL	
Total Bilirubin, or	<2 mg/dL (<34 µmol/L)	2-3 mg/dL (34-50 µmol/L)	>3 mg/dL (>50 µmol/L)	
Modified Total Bilirubin <sup>b</sup>	<4 mg/dL	4–7 mg/dL	>7 mg/dL	
Prothrombin Time (Seconds Prolonged), or	<4	4–6	>6	
International Normalized Ratio (INR)	<1.7	1.7–2.3	>2.3	

<sup>&</sup>lt;sup>a</sup> Encephalopathy Grades

- Grade 1: Mild confusion, anxiety, restlessness, fine tremor, slowed coordination
- Grade 2: Drowsiness, disorientation, asterixis
- Grade 3: Somnolent but rousable, marked confusion, incomprehensible speech, incontinence, hyperventilation
- Grade 4: Coma, decerebrate posturing, flaccidity

<sup>&</sup>lt;sup>b</sup> Modified total bilirubin used for patients who have Gilbert's syndrome or who are taking indinavir or atazanavir.

Child-Pugh Classification	Total Child-Pugh Score <sup>a</sup>
Class A	5–6 points
Class B	7–9 points
Class C	>9 points

<sup>&</sup>lt;sup>a</sup> Sum of points for each component of the Child-Pugh Score.